



Attorney Docket No. CONLINCO-03681

PATENT

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1617

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Asgeir Saebo *et al.*
Serial No.: 09/271,024
Filed: 03/17/99
Entitled: Conjugated Linoleic Acid Compositions

Group No.: 1617
Examiner: Wang, S.

**TRANSMITTAL OF APPLICANT'S REPLY BRIEF
(PATENT APPLICATION - 37 CFR § 192)**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Dated: May 7, 2004

By: Mary Ellen Waite

Mary Ellen Waite

Sir or Madam:

Applicant submits, in triplicate, the REPLY BRIEF to the Examiner's Answer (Paper No. 20040305) mailed March 10, 2004, in the above application. Applicants believe no fee is required, but if the Commissioner deems otherwise, the Commissioner is hereby authorized to charge Deposit Account NO. 02-190 any fees associated with this communication.

Dated: May 7, 2004

J. Mitchell Jones

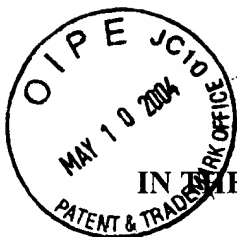
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PATENT

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Serial No.: **09/271,024**

Group No.: **1617**

Filed: **03/17/99**

Examiner: **Wang, S.**

Entitled: **CONJUGATED LINOLEIC ACID COMPOSITIONS**

APPELLANTS' REPLY BRIEF

APPEAL NO.:

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Dated: May 7, 2004

By: 

Mary Ellen Waite

Sir:

This Brief is in reply to the Examiner's Answer (Paper No. 20040305) mailed March 10, 2004.

It is not believed that any fees are necessary for this reply. However, if any fees are necessary, the Examiner is hereby authorized to charge Deposit Account No. 08-1290 the fee associated with this Reply Brief and any other fees associated with this communication. Please reference Attorney Docket No.: CONLINCO-03681 when charging the Attorney Deposit Account. A request for oral examination is being filed concurrently herewith.

This Brief is transmitted in triplicate. [37 C.F.R. § 1.192(a)].

ARGUMENT

The Office's acceptance of the statements of the real party in interest, status of claims, status of amendments after final, summary of invention, and issues, and grouping of the claims is appreciated. However, the Appellants respectfully submit that the Office is mistaken with respect to the lack of a statement of related appeals and interferences. Appellants included the required statement in their Appeal brief. The Office is respectfully directed to Page 3 of the Appeal Brief, where Appellants state: "There are no related appeals or interferences known to Appellants, Appellants' legal representative, or the Assignee."

Below, Appellants specifically address the following issues from the initial Appeal Brief:

Issue 1 – Whether Claims 5 - 8 are anticipated by Cain et al. (WO97/18320).

Issue 2 - Whether Claims 13 - 17 are obvious over Cain et al. (WO97/18320).

Issue 3 - Whether Claims 5 - 8 and 13 - 17 are obvious over Nilsen et al. (U.S. Pat. No. 5,885,594) in view of Cain et al. (WO97/18320), further in view of Pariza et al. (U.S. Pat. No. 5,017,614).

A. Issue 1 - Claims 5-8 Are Not Anticipated by Cain *et al.* (WO97/18320)

Claims 5-8 remain rejected under 35 U.S.C. §102 as allegedly being anticipated by Cain *et al.* (WO97/18320). As argued in the Appeal Brief, the unrebutted evidence on record conclusively establishes that Cain et al. does not anticipate Claim 5 - 8 because the methods utilized by Cain et al. cannot produce the claimed CLA isomer profile (i.e., a CLA composition containing less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-

trans octadecadienoic acid isomers).

Applicants emphatically disagree with the Examiner's assertions on pages 3-4 of the Examiner's Answer that the compositions of Cain contained only the t10,c12 and c9,t11 isomers of CLA. As argued, the Sæbo Declaration establishes that the compositions of Cain et al. necessarily included the 8,10 and 11,13 isomers of CLA. As explained below, the Examiner's Answer has failed to rebut the Applicant's arguments causing reversible error under *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996).

1. *In re Michalek* is not controlling

The Examiner's Answer continues to rely on *In re Michalek* as controlling legal precedent. In so doing, the Examiner has failed to address or rebut the arguments made by Applicants concerning *In re Michalek*. As argued by the Applicants at pages 5-8 of the Appeal Brief, the Office has not analyzed the Declaration and the factual, experimental data contained within it. The Office has still failed to address this argument. The fact remains that the Office has failed to substantively address the data in the Declaration and offer any analysis of why the data is flawed other than that it was produced by the Applicants. As detailed below, this failure to respond to the Applicant's arguments and data is reversible error under *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996).

a) The Office's legal analysis is insufficient

The Office alleges that the Applicants arguments that *In re Michalek* is not controlling is incorrect. In so doing, the Office has failed to address the legal precedent cited by the Applicants and has relied on the sole distinction that "note 'avoid giving evidence no weight' is not 'be

accorded great weight.'" The Examiner's answer is completely silent with respect to cited holdings of *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976) and *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986). As argued in the Appeal Brief, these cases establish that even if the Office had established anticipation or a *prima facie* case of obviousness (and Applicants contend that the Office did not), the Office must respond to the information presented in the Declaration. The above directions of the court and the PTO state that the evidence **must be considered**. These directions do not categorize evidence according to whether it is developed by interested or disinterested parties and do not state that evidence developed by the inventor **may be ignored**. **The directions specifically state that experimental evidence, such as that contained in the Declaration, must be considered.** Indeed, the Examiner must start over and reconsider the entire anticipation or obviousness analysis.

In the present case, there was no reweighing of the merits by the Examiner. Instead of actually analyzing the Declaration and the factual, experimental data contained within it, the Office has summarily dismissed the data with no analysis because it was generated by the Applicants. Applicants submit that the results would be the same no matter who conducts the experiments. The Office has failed to substantively address the data in the Declaration and offer any analysis of why the data is flawed.

b) *In re Michalek* is distinguishable

The Office has cited *In re Michalek* for the proposition that "it is not a difficult matter to carry out a process in such a fashion that it will not be successful and, therefore, the failures of experimenters who have no interest in succeeding should not be accorded great weight."

However, an analysis of the facts *In re Michalek* and the actual language used in *In re Michalek* reveals that it is a case that is limited to its particular facts.

In re Michalek involved claims to a thermoplastic resin comprising polymers or copolymers of one or more nuclear-substituted dichlorostyrenes. *In re Michalek*, 34 C.C.P.A. 1124; 162 F.2d 229; 74 U.S.P.Q. 107 (1947). The court stated the following with respect to the affidavits submitted in support of patentability:

Several affidavits to sustain appellant's contention were filed. In substance it is stated therein that the processes of the Dreisbach patents do not produce monomeric dichlorostyrene sufficiently pure to meet the density and index of refraction recited in the claims or to polymerize, although it is not said that the processes of the patents are incapable of producing the nuclear-substituted dichlorostyrenes mentioned therein. The board considered the affidavits insufficient to overcome the definite naming in those patents of dichlorostyrene and the indication that it is polymerizable. In this connection the solicitor in his brief cites *In re Von Bramer*, 29 C.C.P.A. 1018, 127 F.2d 149, 53 U.S.P.Q. 345.

With respect to the experiments described in the affidavits it must be said that in a patent it is to be presumed that a process, if used by one skilled in the art, will produce the product alleged by the patentee and such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. Skilled workers would as a matter of course, in our opinion, if they do not immediately obtain desired results, make certain experiments and adaptations and we agree with the argument of the solicitor that it is not a difficult matter to carry out a process in such fashion that it will not be successful and, therefore, the failures of experimenters who have no interest in succeeding should not be accorded great weight, citing *Bullard Company et al. v. Coe*, 79 U.S. App. D.C. 369, 147 F.2d 568, 64 U.S.P.Q. 359. Possibly more extensive experiments than were made by the affiants herein might have produced a different result.

It is clear from this discussion that the holding of the court was specific to the facts presented to it, and especially to the nature of the data contained in the affidavits. The court emphasizes this by stating "more extensive experiments" might have "produced a different result." Thus, *In re Michalek* **does not stand** for the proposition that all reproductions of prior art data by an inventor should be ignored simply because the inventor has no reason to be successful. Instead, the court

in *In re Michalek* evaluated the data and found it insufficient. The Office has failed to do this in the instant case. As indicated above, the Office has provided no reasoning as to why the data submitted is insufficient or incorrect. As described in more detail below, this is reversible error.

Furthermore, as indicated in Applicants Appeal Brief, *In re Michalek* is factually distinguishable. The Office has attempted to ignore the evidence provided by Applicants by relying on *In re Michalek* and characterizing the evidence as a failure. To the contrary, the evidence presented by the Applicants is not a failure to repeat the results of Cain et al. Cain et al. is **silent** as to the presence of the 8,10 and 11,13 isomers. The only way the Applicants results could be considered to be a failure is if Cain et al. affirmatively stated that the isomers were not present and then Applicants failed not to produce the isomers. This is not the present situation. Applicants results supplement the teachings of Cain, and do not contradict them.

In particular, the Applicants followed the exact instructions of Cain and analyzed the product. The Applicants did not fail to obtain CLA. Indeed, they obtained CLA with the isomers described by Cain et al. However, the fact remains that the CLA also contained other isomers that are not mentioned by Cain. The fact that Cain is silent with respect to the isomers in Applicants simply should not be held against the Applicants. The data submitted by the Applicants is completely persuasive and unrebutted by the Office. Given this failure, Applicants must request that this issue be resolved in their favor.

c) Failure to adequately rebut the declaration is reversible error

As detailed above, the Office has dismissed the Applicant's arguments and the Sæbo declaration by citing *In re Michalek* and then providing absolutely no other explanation as to why the data contained in the declaration fails to rebut the Office's *prima facie* cases of anticipation

and obviousness. This is reversible error under *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996).

In *In re Alton*, the applicants submitted a declaration in order to rebut a *prima facie* case of inadequate written description by the Board of Appeals in an earlier appeal. *Id.* at 1173. Instead of addressing the arguments presented in the declaration, the Examiner dismissed the declaration as opinion evidence that was entitled to little weight. *Id.* at 1173-745. The Federal Circuit remanded the case to the Board, holding that the Board committed error in both viewing the declaration as opinion evidence and dismissing the declaration "without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case" of unpatentability. *Id.* at 1174. These bases for reversal were independent. With respect failure to provide an adequate explanation of why the declaration failed to rebut the *prima facie* case, the Federal Circuit found that:

In sum, the examiner dismissed the Wall declaration and provided only conclusory statements as to why the declaration did not show that a person skilled in the art would realize that Alton had possession of the claimed subject matter in 1983.

Id. at 1176. In particular, the Federal Circuit held that the examiner failed to address specific points made in the declaration concerning modifications of the amino acids sequence of protein. *Id.*

In re Alton is directly applicable to the present facts. Instead of addressing the arguments presented in the Saebo declaration and the Appeal Brief, the Office has dismissed the Declaration with the conclusory reasoning that it is entitled to "little weight" because it is a repeat of the prior art by an inventor. Thus, under *In re Alton*, the Office has failed to meet the standard for replying to evidence presented in the Sæbo Declaration. Accordingly, Applicants respectfully request that the Examiner's rejection be reversed.

2. The Office has ignored the evidence of similar results by others

At page 5 of the Examiner's Answer, the Office inexplicably argues that: "Further, no other references show that the isomers herein identified would be produced in significant amounts under Cain's conditions, such as those disclosed in Example 6." In sharp contrast, the Applicants have provided such evidence. This evidence was specifically argued in the Appeal Brief at pages 10-11 by reference to Sugano et al., Lipids 33(5):521-527 (1998)(reference 47 in Form 1449 filed April 10, 2000, copy attached to the Appeal Brief at Appendix D for the Office's convenience). Sugano et al. isomerized linoleic acid conditions similar to those described by Cain et al. The conditions utilized in the two references are compared in following Table.

Cain et al., Example 1	Sugano et al.
50 g linoleic acid, 95% pure	50 g linoleic acid, 99% pure
Solvent: 290 grams ethylene glycol	Solvent: 290 grams ethylene glycol
Catalyst: 15 g NaOH	Catalyst: 15 g NaOH
Reaction time: 2 hours	Reaction time: 2 hours
Reaction temperature: 180° C	Reaction temperature: 180° C
Reaction atmosphere: Inert	Reaction atmosphere: Nitrogen

As can be seen, the reaction conditions were almost identical. However, the results are not. As noted on page 522 of Sugano, the resulting CLA preparation contained the following CLA isomers: 29.8% c9,t11/t9,c11; 29.6% t10,c12; 1.3% c9,c11; 1.4% c10,c12; 18.6% t9,t11/t10,t12; 5.6% linoleic acid; and 13.7% other isomers. In contrast to the simplified analysis presented in Cain et al., isomerization of CLA results in the production of many different isomers, not just the

desired c9,t11 and t10,c12 isomers.

The Office's complete failure to address this evidence is again grounds for reversal. The Office refers to Example 6 instead of Example 1, however Example 6 of Cain is merely a slightly larger scale production of CLA than Example 1. The ultimate result of the process would be the same - the production of many other isomers of CLA than just the c9,t11 and t10,c12 isomers.

3. The Office ignored other evidence of the production of multiple isomers

In the Appeal Brief, the Applicants also presented other evidence that establishes that the processes used by Cain et al. produce multiple isomers other than c9,t11 and t10,c12 isomers. In particular, Applicants argued that it is impossible to isomerize linoleic acid by the methods described in Cain without producing other isomers due to the process known as thermal sigmatropic rearrangement. This process is described in Chapter 5 of the book *Advances in Conjugated Linoleic Acid Research, Volume 2*, J. Sebedio, W.W. Christie, and R. Adolf, Eds., AOCS Press, Champaign, IL, 2002 (Attached to the Appeal Brief as Appendix C). Mr. Saebo wrote this chapter. Briefly, the research described in this chapter establishes that the formation of the 8,10 and 11,13 isomers is a necessary consequence of heating compositions containing the t10,c12 and c9,t11 isomers. Thus, whenever compositions containing t10,c12 and c9,t11 CLA are heated at temperatures such as those used by Cain et al. (i.e., 180°C for about 2 - 2.5 hours), 8,10 and 11,13 isomers are necessarily produced. Accordingly, it appears that Cain et al. simply failed to conduct an analysis for the other isomers present in the isomerized product since those isomers were necessarily present.

Applicants have **failed to find any reference** to this argument in the Examiner's answer. Thus, the argument stands completely un rebutted. Accordingly, Applicants request that the

Examiner's rejection be reversed.

B. Issue 2 - Claims 13-17 Are Not Obvious Over WO97/18320

Claims 13-17 stand rejected under 35 U.S.C. §103 as allegedly being obvious over Cain *et al.* (WO97/18320). Applicants respectfully note that a *prima facie* case of obvious requires that all elements of the claims be present in the cited reference. As established above, the compositions of Cain necessarily contained levels 8,10; 11,13; and trans,trans isomers that do not meet the claimed levels. Thus, Cain *et al.* does not render the claims obvious because Cain does not teach each element of the claims. Accordingly, Applicants respectfully request that this ground of rejection be removed and the claims passed to allowance.

C. Issue 3 - Claims 5-8 and 13-17 Are Not Obvious Over the Combination of Nilsen, Cain and Pariza

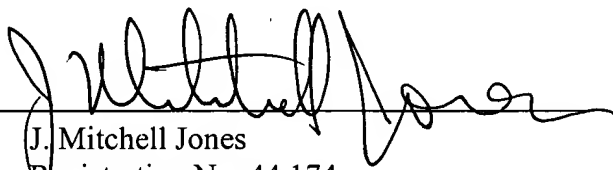
Claims 5-8 and 13-17 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious under Nilsen *et al.* (U.S. Pat. No. 5,885,594) in view of Cain *et al.* (WO97/18320), further in view of Pariza *et al.* (US Pat. No. 5,017,614). The Office has failed to establish a *prima facie* case of obviousness because the references, alone or in combination, fail to teach each element of the claimed compositions. In particular, the combined references do not teach acylglyceride compositions comprising less than 1% 8,10; 11,13; and trans-trans isomers and containing at least approximately 30% t10,c12 and 30% c9,t11 isomers.

The Office's sole response to the arguments presented in the Appeal Brief is that "[I]n response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references." This statement does not apply to the arguments advanced by the Applicants. The Applicant's argument is that none of the references, alone or combined, teach each elements of the claims. Applicants then demonstrated this fact by discussing each reference in turn and demonstrating that none of the references teach the element of containing less than 1% 8,10; 11,13; and trans-trans isomers of CLA. Thus, Applicants did not attack each reference individually, the Applicants demonstrated that the references do not teach a claim element. Moreover, the Applicants established that Pariza actually teaches away from the claimed compositions and thus cannot be used as motivation to combine or modify the references. *See Tec Air, Inc. v. Denso Manufacturing Michigan, Inc.*, 192 F.3d 1353. The Office again completely failed to address this argument. Accordingly Applicants respectfully request that the Examiner's rejection be reversed.

D. Conclusion

For the foregoing reasons, it is submitted that the Office's rejection of Claims 5 - 8 and 13 - 17 was erroneous, and reversal of the rejection is respectfully requested. Appellant requests either that the Board render a decision as to the allowability of the claims, or alternatively, that the application be remanded for reconsideration by the Office.

Dated: May 7, 2004
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APPENDIX A

CLEAN VERSION OF THE ENTIRE SET OF PENDING CLAIMS

5. (Amended three times) A biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R₁, R₂, and R₃ attached at the positions of the OH- groups of a glycerol backbone, and wherein R₁, R₂, and R₃ are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R₁, R₂, and R₃, wherein said percentages are peak area percentages as determined by gas chromatography.

6. The composition of claim 5, further comprising a food product incorporating said acylglycerol composition.

7. The composition of claim 6, wherein said food product is for human consumption.

8. The composition of claim 6, wherein said food product is a feed formulated for animal consumption.

13. (Amended three times) A composition comprising a prepared food product containing a biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R₁, R₂, and R₃ attached at the positions of the OH- groups of a glycerol backbone, and wherein R₁, R₂, and R₃ are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R₁, R₂, and R₃, wherein said percentages are peak area percentages as determined by gas chromatography.

14. The composition of Claim 13, wherein said prepared food product is a bar.

15. The composition of Claim 13, wherein said prepared food product is a drink.
16. The composition of Claim 13, wherein said prepared food product is a snack food.
17. The composition of Claim 13, wherein said prepared food product is a frozen meal.